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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/695,347 | 10/28/2003 | Shun-Por Li | MCP-5007 | 5595 |
| 27777 | 7590 | 01/22/2007 | EXAMINER | |
| PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003 | | | WEBMAN, EDWARD J | |
| | | ART UNIT | PAPER NUMBER | |
| | | | | 1616 |
| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | | DELIVERY MODE | |
| 3 MONTHS | 01/22/2007 | | PAPER | |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| | | | |
|------------------------------|------------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/695,347 | LI ET AL. | |
| | Examiner Edward J. Webman | Art Unit 1616 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 28 October 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 14-16 and 29-31 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-13,28 and 75 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>10/28/03, 1/30/06</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____. |

Claim 2 (exemplary) is generic to the following disclosed patentably distinct species: polymers. The species are independent or distinct because each polymer has a distinct chemical structure which imparts distinct chemical and physical properties. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

This application contains claims directed to the following patentably distinct species: a dosage form wherein the claimed composition is in a shell, a dosage form wherein the claimed composition is in a core, an aqueous dosage form. The species are independent or distinct because each has a distinct physical form which imparts distinct properties of delivery.

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Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, dosage forms are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

During a telephone conversation with D. Crichton on 1/4/06 a provisional election was made with traverse to prosecute the invention of HPMC and a dosage form wherein the claimed composition is in both a shell and core. Affirmation of this election must be made by applicant in replying to this Office action. Claims 14-16 and 29-31 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-13, 17-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Joshi et al in view of Chang et al and Raiden et al.

Joshi et al teach beadlets comprising an active and a binder (abstract). 3-70 % binder, including the hydrocolloid hydroxypropylmethyl cellulose with a viscosity of 2-200 cp, is disclosed (column 9 line 66-column 10 line 22). Other hydrocolloids, including carrageenan, may be employed (column 10 lines 23-30). Lubricants are disclosed (column 5 lines 41).

Chang et al teach partially deacylated gellan gum which forms elastic gels having low brittleness (abstract).

It would have been obvious to one of ordinary skill to add a partially deacylated gellan gum to the beadlet of Joshi et al to achieve the beneficial effect of modifying its flexibility in view of Chang et al.

As to the percent range and viscosity of hydroxypropylmethylcellulose, Joshi et al teach a range which overlaps those claimed. As to the claimed cloud point range, it is argued that the polymer of Joshi et al inherently possesses such a range, because it is the same polymer as that claimed. As to the claimed ranges of the other ingredients, optimum suitable amounts may be obtained by routine experimentation, absent a showing that they are essential or provide an unexpected result. In re Boesch 205

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USPQ 215 (CCPA 1980). As to the particular claimed lubricant, glyceryl monostearate, Raiden et al teach that it is well known in the art as such (column 5, lines 3-10). Thus, it would have been further obvious to add glyceryl monostearate to the composition of Joshi et al for its beneficial effect as a lubricant in view of Raiden et al.

As to the claimed shell, it is argued that if the shell comprises the same composition as the core, they become indistinguishable. As to the claimed shell portion and core portion, "portion" includes 100 %. As to the claimed burst release, such is merely an intended use. As to the claimed substantial freedom from pores of the claimed range, Joshi et al do not disclose pores of any size.

Claims 1-13, 17-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1 and 17, "high" is vague because it is suggestive. In claims 5 and 21, "inorganic cation" has no antecedent in claims 1 and 17 respectively. Similarly, in claims 7 and 17, "lubricant" has no antecedent in claims 1 and 17 respectively. In claim 8, it is unclear as to whether the diameter of the pores or the diameter of the solid form is being claimed.

No claims allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward J. Webman whose telephone number is 571-272-0633. The examiner can normally be reached on M-F from 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, J. Richter, can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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